PMA Monthly approvals from 4/1/2016 to 4/30/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130001	04/12/2016	PMAO - PMA Origi	Epi proColon	EPIGENOMICS AG	The Epi proColon test is a qualitative in vitro diagnostic test for the detection of methylated Septin 9 DNA in EDTA plasma derived from patient whole blood specimens. Methylation of the target DNA sequence in the promoter region of the SEPT9_v2 transcript has been associated with the occurrence of colorectal cancer (CRC). The test uses a real-time polymerase chain reaction (PCR) with a fluorescent hydrolysis probe for the methylation specific detection of the Septin 9 DNA target. The Epi proColon test is indicated to screen adults of either sex, 50 years or older, defined as average risk for CRC, who have been offered and have a history of not completing CRC screening. Tests that are available and recommended in the USPSTF 2008 CRC screening guidelines should be offered and declined prior to offering the Epi proColon test. Patients with a positive Epi proColon test result should be referred for diagnostic colonoscopy. The Epi proColon test results should be used in combination with physician's assessment and individual risk factors in guiding patient management.

Data as of05/20/2016 04:15AM

P150012	04/25/2016	PMAO - PMA Origi	IMAGEREADY MR CONDITIONAL PACING SYSTEM AND INGEVITY PACE/SENSE LEAD	BOSTONSCIENTIFIC	Approval for The ImageReady MR Conditional Pacing System. The device is indicated for the treatment of the following conditions: 1) Symptomatic paroxysmal or permanent second- or third-degree AV block; 2) Symptomatic bilateral bundle branch block; 3) Symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders (i.e., sinus bradycardia, sinus arrest, sinoatrial [SA] block); 4) Bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; and 5) Neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of the following: 1) Conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; 2) VVI intolerance (i.e., pacemaker syndrome) in the presence of persistent sinus rhythm; and 3) Low cardiac output or congestive heart failure secondary to bradycardia. Passive-fixation Non-MRI Models 7631, 7632, 7635 and 7636 and MRI Models 7731, 7732, 7735 and 7736 are indicated for chronic pacing and sensing in the right atrium (Preformed Atrial J) or right ventricle (Straight) when used with a compatible pulse generator. Active-fixation Non-MRI Models 7640, 7641, and 7642 and MRI Models 7740, 7741, and 7742 are indicated for chronic pacing and sensing in the right atrium and/or right ventricle when used with a compatible pulse generator. The intended use of the slit suture sleeve accessory is to secure and immobilize Boston Scientific Ingevity leads at the venous entry site. The delivery stylet accessory is indicated for use with Boston Scientific implantable transvenous leads.
P150016	04/11/2016	PMAO - PMA Origi	TRIDYNE VASCULAR SEALANT	NEOMEND, INC.	The Tridyne Vascular Sealant is indicated for use in aortic surgery when adjunctive measures to achieve hemostasis are required by mechanically sealing areas of leakage.
P150026	04/01/2016	PMAO - PMA Origi	HEARTLIGHT ENDOSCOPIC ABLATION SYSTEM	CARDIOFOCUS, INC.	The HeartLight® Endoscopic Ablation System is indicated for the treatment of drug refractory recurrent symptomatic paroxysmal atrial fibrillation

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P150033	04/06/2016	PMAO - PMA Origi	MEDTRONIC MICRA TRANSCATHETER PACEMAKER SYSTEM	MEDTRONIC INC.	Approval for the Micra Transcatheter Pacemaker System (Pacemaker Model MC1VR01 and Programmer Application Software model SW022 Version 1.1). This device is indicated for use in patients who have experienced one or more of the following conditions: symptomatic paroxysmal or permanent high-grade AV block in the presence of AF symptomatic paroxysmal or permanent high-grade AV block in the absence of AF, as an alternative to dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy symptomatic bradycardia-tachycardia syndrome or sinus node dysfunction (sinus bradycardia or sinus pauses), as an alternative to atrial or dual chamber pacing, when atrial lead placement is considered difficult, high risk, or not deemed necessary for effective therapy Rate-responsive pacing is indicated to provide increased heart rate appropriate to increasing levels of activity.
P150041	04/11/2016	PMAO - PMA Origi	VYSIS CLL FISH PROBE KIT	ABBOTT MOLECULAR, INC.	The Vysis CLL FISH Probe Kit is a test to detect deletion of the LSI TP53 probe target via fluorescence in situ hybridization (FISH) in peripheral blood specimens from patients with B-cell chronic lymphocytic leukemia (CLL). The test is indicated for detecting deletion of the LSI TP53 probe target (17p-) as an aid in identifying those patients with CLL for whom treatment with VENCLEXTA® (venetoclax) is indicated. Vysis CLL FISH Probe Kit is not intended for monitoring of residual disease.

Total: 6

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N16837/S019	04/04/2016	R - Real-Time Proc	ARTEGRAFT COLLAGEN VASCULAR GRAFT	ARTEGRAFT, INC.	Approval for the use of new polymers for the button and rod that are used in the primary packaging system for this device.
P790007/S047	04/28/2016	R - Real-Time Proc	THE HANCOCK VALVED CONDUIT MODIFIED ORIFICE (MODEL 105)	MEDTRONIC HEART VALVES	Approval for packaging and labeling changes for the Hancock Valved Conduit Modified Orifice (Model 105) and the Hancock Valved Conduit Low Porosity (Model 150).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P840001/S242	04/29/2016	R - Real-Time Proc	ITREL EZ PATIENT PROGRAMMER,SYNERGY EZ PATIENT PROGRAMMER,ACCESS THERAPY PATIENT CONTROLLER	MEDTRONIC INC.	Approval for the replacement of the battery compartment labels of the hand-held patient programmers with labels whole pressure sensitive is resistant to the effects of high humidity.
P840001/S321	04/21/2016	N - Normal 180 Day		MEDTRONIC NEUROMODULATION	Approval for changes made to the Model 8840 N'Vision® Clinician Programmer including replacement of PCBA components, liquid crystal display assembly changes, compact flash card housing and programmer housing design changes, infrared data association transceiver changes, static random access memory changes, electromagnetic interference shield changes, telemetry module platform software updates, clinical programmer base module platform software updates, Physician Manual labeling changes, EMC Declaration changes, device labeling changes and packaging labeling changes.
P860003/S083	04/08/2016	R - Real-Time Proc	THERAKOS CELLEX PHOTOPHERESIS SYSTEM PROCEDURAL KIT	THERAKOS, INC.	Approval for a change in the color scheme of the anticoagulant line from green-striped to orange-striped, and in the color of the anticoagulant spike chamber from white to orange.
P860004/S246	04/21/2016	N - Normal 180 Day	MEDTRONIC(R) SYNCHROMED(TM) PUMP & INFUSION SYSTEM	MEDTRONIC INC.	Approval for changes made to the Model 8840 N'Vision® Clinician Programmer including replacement of PCBA components, liquid crystal display assembly changes, compact flash card housing and programmer housing design changes, infrared data association transceiver changes, static random access memory changes, electromagnetic interference shield changes, telemetry module platform software updates, clinical programmer base module platform software updates, Physician Manual labeling changes, EMC Declaration changes, device labeling changes and packaging labeling changes.
P870078/S031	04/28/2016	R - Real-Time Proc	THE HANCOCK VALVE CONDUIT LOW POROSITY (MODEL 150)	MEDTRONIC INC.	Approval for packaging and labeling changes for the Hancock Valved Conduit Modified Orifice (Model 105) and the Hancock Valved Conduit Low Porosity (Model 150).
P880086/S263	04/28/2016	Y - 135 Review Tra	VICTORY, ZEPHYR, ACCENT, ASSURITY, ASSURITY+, ENDURITY, IDENTITY ADX, VERITY ADX	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P890003/S350	04/28/2016	R - Real-Time Proc	CareLink Programmer (Model 2090), Encore Programmer (Model 29901)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for software changes to the Reveal LINQ FullView Application Software.
P890003/S351	04/29/2016	R - Real-Time Proc	MyCareLink Patient Monitor Model 24950	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware updates to the MyCareLink Patient Monitor.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P890003/S353	04/26/2016	R - Real-Time Proc	CARELINK INSTRUMENT COMMAND LIBRARY, MEDTRONIC CARELINK MONITOR, MYCARELINK PATIENT MONITOR.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for minor software updates to the Instrument Command Library (ICL) Model 2691 to provide support for the Visia AF family of devices.
P890064/S033	04/15/2016	R - Real-Time Proc	digene Hybrid Capture 2 (HC2) HPV DNA Test and digene Hybrid Capture 2 (HC2) High Risk	QIAGEN GAITHERSBURG, INC	Approval for a new version of the HC2 Software Suite (version 4.4) and a new hardware model of the PC used with this software.
P910001/S085	04/13/2016	S - Special CBE	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Approval for the addition of warnings to the Directions for Use (DFU) of the associated Laser Catheters included in the Laser System.
P910023/S365	04/28/2016	Y - 135 Review Tra	CURRENT+, FORTIFY, FORTIFY ASSURA, ELLIPSE	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P910023/S370	04/21/2016	R - Real-Time Proc	CURRENT+ ELLIPSE, FORTIFY ASSURA FAMILIES OF THE ICD DEVICES	St. Jude Medical	Approval for design change to high voltage capacitors.
P910073/S133	04/29/2016	Y - 135 Review Tra	ENDOTAK RELIANCE IS-1 AND ENDOTAK RELIANCE 4-SITE LEAD MODELS	BOSTON SCIENTIFIC	Approval for the removal of redundant specifications and testing associated with batch release and drug stability testing.
P920015/S166	04/28/2016	N - Normal 180 Day	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD MODEL 6935M,SPRINT QUATTRO SECURE MRI SURESCAN LEAD MODEL 6947M	MEDTRONIC INC.	Approval for the expansion of MRI conditional labeling for the Advisa and Evera SureScan systems to 3T MRI.
P920047/S088	04/28/2016	Y - 135 Review Tra	BLAZER PRIME HTD,BLAZER II,BLAZER II HTD TEMPERATURE ABLATION CATHETERS	BOSTON SCIENTIFIC CORP.	Approval for a vendor change to manufacture the tube braid component, including a resin material change, used on the ablation catheters.
P930038/S077	04/29/2016	O - Normal 180 Day	ANGIO-SEAL STS+,ANGIO-SEAL VIP, AND ANGIO-SEAL EVOLUTION VASCULAR CLOSURE DEVICES	ST. JUDE MEDICAL, INC.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P930039/S142	04/28/2016	N - Normal 180 Day	CAPSUREFIX NOVUS MRI SURESCAN LEAD MODEL 5076	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the expansion of MRI conditional labeling for the Advisa and Evera SureScan systems to 3T MRI.
P950009/S020	04/19/2016	O - Normal 180 Day	AUTOPAP(R) 300 QC AUTOMATIC PAP SCREENER/QC SYSTEM	BD DIAGNOSTICS	Approval for a manufacturing site located at BD Diagnostics, 7 Loveton Circle, Sparks, MD 21152.
P950022/S089	04/28/2016	Y - 135 Review Tra	DURATA, DURATA, OPTISURE	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P950037/S160	04/13/2016	R - Real-Time Proc	ACROS DR/SR/SLR/D/S,AXIOS DR/SR/SLR/D/S,BA03 DDDR,CYLOS DR/DR-T/VR,DROMOS DR/SR/SL,KAIROS DR/SR/SL/D/S,PHILOS DR/DR-T/S	BIOTRONIK, INC.	Approval for the PSW 1506.U Programmer Software.
P960004/S075	04/29/2016	Y - 135 Review Tra	FINELINE II STEROX AND STEROX EZ LEADS	BOSTON SCIENTIFIC	Approval for the removal of redundant specifications and testing associated with batch release and drug stability testing.
P960009/S173	04/29/2016	R - Real-Time Proc	ACCESS THERAPY PATIENT CONTROLLER,ACCESS REVIEW THERAPY CONTROLLER	MEDTRONIC INC.	Approval for the replacement of the battery compartment labels of the hand-held patient programmers with labels whole pressure sensitive is resistant to the effects of high humidity.
P960009/S246	04/21/2016	N - Normal 180 Day	MEDTRONIC ACTIVA TREMOR CONTROL SYSTEM	MEDTRONIC INC.	Approval for changes made to the Model 8840 N'Vision® Clinician Programmer including replacement of PCBA components, liquid crystal display assembly changes, compact flash card housing and programmer housing design changes, infrared data association transceiver changes, static random access memory changes, electromagnetic interference shield changes, telemetry module platform software updates, clinical programmer base module platform software updates, Physician Manual labeling changes, EMC Declaration changes, device labeling changes and packaging labeling changes.
P960013/S078	04/28/2016	Y - 135 Review Tra	TENDRIL SDX LEAD, TENDRIL ST LEAD, OPTISENSE, TENDRIL STS LEAD	PACESETTER, INC.	Approval for the reassessment of microbiological levels for cleanrooms.
P960016/S056	04/29/2016	O - Normal 180 Day	LIVEWIRE CARDIAC ABLATION SYSTEM	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.

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P960030/S040	04/28/2016	Y - 135 Review Tra	ISOFLEX OPTIM	PACESETTER, INC.	Approval for the reassessment of microbiological levels for cleanrooms.
P960042/S053	04/13/2016	S - Special CBE	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM & LASER SHEATH	SPECTRANETICS CORP.	Approval for the addition of warnings to the Directions for Use (DFU) of the associated Laser Catheters included in the Laser System.
P970003/S190	04/29/2016	R - Real-Time Proc	VNS THERAPY SYSTEM	CYBERONICS, INC.	Approval for a new serial adapter cable to connect the programming computer to the programming wand.
P970004/S210	04/21/2016	N - Normal 180 Day	MEDTRONIC INTERSTIM THERAPY SYSTEM FOR URINARY CONTROL	MEDTRONIC NEUROMODULATION	Approval for changes made to the Model 8840 N'Vision® Clinician Programmer including replacement of PCBA components, liquid crystal display assembly changes, compact flash card housing and programmer housing design changes, infrared data association transceiver changes, static random access memory changes, electromagnetic interference shield changes, telemetry module platform software updates, clinical programmer base module platform software updates, Physician Manual labeling changes, EMC Declaration changes, device labeling changes and packaging labeling changes.
P970013/S067	04/28/2016	Y - 135 Review Tra	MICRONY	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P970058/S027	04/26/2016	O - Normal 180 Day	IMAGE CHECKER, IMAGE CHECKER LICENSE	HOLOGIC, INC.	Approval for a manufacturing site located at Hologic, Inc., 35 Crosby Drive, Bedford, Massachusetts.
P980016/S555	04/28/2016	N - Normal 180 Day	EVERA MRI XT DR/VR SURESCAN,EVERA MRI S DR/VR SURESCAN ICDS AND PROGRAMMER SOFTWARE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for the expansion of MRI conditional labeling for the Advisa and Evera SureScan Systems to 3T MRI.
P980016/S572	04/22/2016	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a dimensional change to the connector module seal.
P980016/S581	04/29/2016	R - Real-Time Proc	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware update to the MyCareLink Patient Monitor

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P980016/S585	04/26/2016	R - Real-Time Proc	VISIA AF VR, VISIA AF MRI VR SURESCAN, EVERA S DR ICD, EVERA S VR ICD,EVERA XT DR ICD, EVERA XT VR ICD, MAXIMO II ICD, PROTECTA ICD, PROTECTA XT ICD, SECURA ICD, VIRTUOSO II DR/VR ICD.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMEN T	Approval for minor software updates to the Instrument Command Library (ICL) Model 2691 to provide support for the Visia AF family of devices.
P980035/S442	04/28/2016	N - Normal 180 Day	ADVISA MRI DR/SR SURESCAN IPGS AND PROGRAMMER SOFTWARE	MEDTRONIC INC.	Approval for expansion of MRI conditional labeling for the Advisa and Evera SureScan systems to 3T MRI.
P980035/S460	04/29/2016	R - Real-Time Proc	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Approval for firmware update to the MyCareLink Patient Monitor.
P980037/S057	04/22/2016	O - Normal 180 Day	ANGIOJET RHEOLYTIC THROMBECTOMY LF140 CATHETER	BOSTON SCIENTIFIC CORP.	Approval for a dual manufacturing site located at Boston Scientific Corporation, 150 Baytech Drive, San Jose, California, for final manufacturing activities, which include incoming inspection, acceptance testing, final packaging, and labeling.
P980053/S016	04/06/2016	S - Special CBE	DURASPHERE INJECTABLE BULKING AGENT	CARBON MEDICAL TECHNOLOGI ES, INC.	Approval for the addition of an inspection procedure for the verification of shipments to the sterilization vendor; the addition of instructions into an existing manufacturing procedure to document sealer settings on the record; the addition of instructions into an existing manufacturing procedure to record additional information and verify the total amount of sterile water used; and to revise latex labeling in line with recent FDA guidance.
P990081/S034	04/13/2016	Y - 135 Review Tra	PATHWAY ANTI-HER-2/NEU (4B5)RABBIT MONOCLONAL PRIMARY ANTIBODY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the following: 1) Enlargement of a bulk formulation room at Ventana Medical Systems' Tucson, AZ facility; and 2) addition of two large volume tanks, along with supply plumbing, a clean in place (CIP) procedure, and new filler, as well as a new fill line.
P000009/S064	04/13/2016	R - Real-Time Proc	BELOS DR/DR-T/VR-VR-T LEXOS DR/DR-T/VR-VR-T; LUMOS DR-T/VR-T; XELOS DR-T	BIOTRONIK, INC.	Approval for the PSW 1506.U Programmer Software.
P000025/S085	04/29/2016	R - Real-Time Proc	THE MED-EL C40 + COCHLEAR IMPLANT	MED-EL CORP.	Approval for labeling the MED-EL C40+ cochlear implant as conditionally safe for 1.5 Tesla in magnetic resonance (MR) environments, and updating the C40+ labeling with information on radiation therapy and scuba diving for patients and professionals.
P000039/S052	04/29/2016	O - Normal 180 Day	AMPLATZER SEPTAL OCCLUDER,CRIBRIFORM OCLUDER,AND DELIVERY AND EXCHANGE SYSTEMS	AGA MEDICAL CORP.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S407	04/29/2016	Y - 135 Review Tra	ACUITY SPIRAL LEAD MODELS	BOSTON SCIENTIFIC CORP.	Approval for the removal of redundant specifications and testing associated with batch release and drug stability testing.
P010015/S297	04/29/2016	R - Real-Time Proc	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Approval for firmware update to the MyCareLink Patient Monitor.
P010030/S072	04/26/2016	R - Real-Time Proc	LIFEVEST WEARABLE DEFIBRILLATOR	ZOLL MANUFACTURING CORPORATION	Approval for modifications to the currently approved garment.
P010031/S530	04/15/2016	R - Real-Time Proc	BRAVA CRT-D,BRAVA QUAD CRT-D,VIVA QUAD S CRT-D,VIVA QUAD XT CRT-D,VIVA S CRT-D,VIVA XT CRT-D,CRT-D MRI AMPLIA,CRT-D MRI	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for minor design and manufacturing changes associated with a component on the hybrid (Telemetry M Module) used in Medtronic ICD and CRT devices.
P010031/S533	04/22/2016	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for a dimensional change to the connector module seal.
P010031/S543	04/29/2016	R - Real-Time Proc	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for firmware update to the MyCareLink Patient Monitor.
P010031/S546	04/26/2016	R - Real-Time Proc	BRAVA, BRAVA QUAD, CONCERTO II, CONSULTA, MAXIMO II, PROTECTA, PROTECTA XT, VIVA QUAD S, VIVA QUAD XT, VIVA S, VIVA XT CRT-D; AMPLIA MRI CRT-D SURESCAN, AMPLIA MRI QUAD CRT-D SURESCAN, COMPIA MRI CRT-D SURESCAN, COMPIA MRI QUAD CRT-D SURESCAN.	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for minor software updates to the Instrument Command Library (ICL) Model 2691 to provide support for the Visia AF family of devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S100	04/29/2016	O - Normal 180 Day	GENESIS EON,EONC,EON MINI,PROTEGE,PROTEGE MRI,AND PROCLAIM FAMILY SPINAL CORD STIMULATION (SCS) SYSTEMS	St. Jude Medical	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113 for rework/relabeling of 12 class III devices.
P010047/S032	04/15/2016	N - Normal 180 Day	PROGEL PLEURAL AIR LEAK SEALANT WITH RECOMBINANT HUMAN ALBUMIN	NEOMEND, INC.	Approval to add a model that changes the source material for the protein solution from Human Serum Albumin (HSA) to recombinant Human Albumin (rHA for the Progel® Pleural Air Leak Sealant (PALS) with Recombinant Human Albumin (rHA) .
P020012/S012	04/21/2016	Y - 135 Review Tra	ARTEFILL, BELLAFILL PMMA COLLAGEN PERMANENT DERMAL FILLER	SUNEVA MEDICAL, INC.	Approval for changes in the manufacturing process to remove a sampling step, split sterilization batch records, and add re-sieving steps.
P020014/S045	04/28/2016	O - Normal 180 Day	ESSURE SYSTEM	BAYER PHARMA AG	Approval for modifications to the post-approval study protocol.
P020024/S041	04/29/2016	O - Normal 180 Day	AMPLATZER DUCT OCCLUDER AND DELIVERY AND EXCHANGE SYSTEMS	AGA MEDICAL CORP.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P020025/S082	04/28/2016	Y - 135 Review Tra	BLAZER PRIME XP,INTELLATIP MIFI XP, BLAZER II XP TEMPERATURE ABLATION CATHETERS	BOSTON SCIENTIFIC	Approval for a vendor change to manufacture the tube braid component, including a resin material change, used on the ablation catheters.
P020055/S018	04/13/2016	Y - 135 Review Tra	VENTANA PATHWAY ANTI-C-KIT PRIMARY ANTIBODY (POLYCLONAL)	VENTANA MEDICAL SYSTEMS, INC.	Approval for the following: 1) Enlargement of a bulk formulation room at Ventana Medical Systems' Tucson, AZ facility; and 2) addition of two large volume tanks, along with supply plumbing, a clean in place (CIP) procedure, and new filler, as well as a new fill line.
P030011/S039	04/15/2016	R - Real-Time Proc	SYNCARDIA CAMPANION 2 DRIVER SYSTEM	SYNCARDIA SYSTEMS, INC.	Approval for a design change in the power cord.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030011/S043	04/27/2016	S - Special CBE	SYNCARDIA TEMPORARY CARDIO WEST TOTAL ARTIFICIAL HEART (TAH-T)	SYNCARDIA SYSTEMS, INC.	Approval for customer notifications regarding state of charge for batteries separate from consoles in air transportation.
P030017/S235	04/28/2016	N - Normal 180 Day	PRECISION MONTAGE MRI SPINAL CORD STIMULATOR SYSTEM, PRECISION MONTAGE SPINAL CORD STIMULATOR SYSTEM	BOSTON SCIENTIFIC CORP.	addition of the PrecisionTM MontageTM MRI and PrecisionTM MontageTM System Components
P030035/S141	04/28/2016	Y - 135 Review Tra	ANTHEM, ALLURE, ALLURE RF, ALLURE QUADRA, ALLURE QUADRA RF	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P030054/S295	04/28/2016	Y - 135 Review Tra	PROMOTE+, UNIFY, UNIFY QUADRA, UNIFY ASSURA, QUADRA ASSURA, QUICKFLEX U, QUARTET	St. Jude Medical	Approval for the reassessment of microbiological levels for cleanrooms.
P030054/S301	04/21/2016	R - Real-Time Proc	PROMOTE+ QUADRA ASSURA , UNIFY ASSURA, UNIFY QUADRA FAMILIES OF CRT-D DEVICES	St. Jude Medical	Approval for a design change to high voltage capacitors.
P030054/S301	04/21/2016	R - Real-Time Proc	PROMOTE+ QUADRA ASSURA , UNIFY ASSURA, UNIFY QUADRA FAMILIES OF CRT-D DEVICES	ST. JUDE MEDICAL	Approval for a design change to high voltage capacitors.
P040014/S026	04/29/2016	O - Normal 180 Day	THERAPY CARDIAC ABLATION CATHETER	IRVINE BIOMEDICAL, INC.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P040040/S024	04/29/2016	O - Normal 180 Day	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORP.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P040042/S031	04/29/2016	O - Normal 180 Day	THERAPY DUAL 8 CATHETER,THERAPY 8MM THERMISTOR ABLATION CATHETER, SAFIRE TX, AND ASSOCIATED CABLES	IRVINE BIOMEDICAL,INC.(IBI)	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050023/S093	04/13/2016	R - Real-Time Proc	IFORIA 5/7 DR-T/VR-T/VR-T DX; INVENTRA 7 DR-T/VR-T/VR-T DX; IPERIA 5/7 DR-T/VR-T/VR-T DX; LUMAX 300/340 DR/DR-T/VR/VR-T	BIOTRONIK, INC.	Approval for the PSW 1506.U Programmer Software.
P050037/S069	04/12/2016	Y - 135 Review Tra	RADIESSE INJECTABLE IMPLANT	MERZ NORTH AMERICA, INC	Approval for changes in the manufacturers of chemicals used in the Radiesse manufacturing process.
P050039/S017	04/12/16	O - Normal 180 Day	NOVATION CERAMIC ARTICULATION HIP	EXACTECH, INC.	Approval for a manufacturing site located at Orchid Detroit 23149 Commerce Drive, Farmington Hills, Michigan, 48335.
P050047/S052	04/29/2016	S - Special CBE	JUVEDERM 24HV, JUVEDERM 30 AND JUVEDERM 30HV GEL IMPLANTS	ALLERGAN	Approval for changes to the Directions for Use and Patient Labeling including updated postmarket surveillance data as well changes to harmonize pertinent content across Juvederm labeling documents. Minor typographical revisions and clarificatio included.
P050052/S080	04/12/2016	Y - 135 Review Tra	RADIESSE (+) LIDOCAINE DERMAL FILLER	MERZ NORTH AMERICA, INC	Approval for changes in the manufacturers of chemicals used in the Radiesse manufacturing process.
P060006/S073	04/19/2016	R - Real-Time Proc	BOSTON SCIENTIFIC EXPRESS SD RENAL MONORAIL PREMOUNTED STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a finishing change and vendor change for a delivery system component.
P060019/S033	04/29/2016	O - Normal 180 Day	THERAPY COOL PATH ABLATION CATHETER, THERAPY COOL PATH SP ABLATION CATHETE, SAFIRE BLU ABLATION CATHETER, SAFIRE BLU SP	IRVINE BIOMEDICAL, INC.	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/ class III devices.

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P060019/S033	04/29/2016	O - Normal 180 Day	THERAPY COOL PATH ABLATION CATHETER, THERAPY COOL PATH SP ABLATION CATHETE, SAFIRE BLU ABLATION CATHETER, SAFIRE BLU SP	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P060040/S054	04/05/2016	S - Special CBE	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Approval for adding an informational card related to the backup battery.
P070007/S038	04/05/2016	O - Normal 180 Day	TALENT THORACIC STENT GRAFT SYSTEM	MEDTRONIC VASCULAR	Approval of the following changes to the post-approval study for the device: sponsor proposes to terminate its THRIVE Trial PAS due to the device no longer being manufactured or commercially available.
P070008/S069	04/13/2016	R - Real-Time Proc	STRATOS LV/LV-T, EVIA HF/HF-T; ENTOVIS HF/HF-T	BIOTRONIK, INC.	Approval for the PSW 1506.U Programmer Software.
P070015/S132	04/27/2016	Y - 135 Review Tra	XIENCE V AND XIENCE NANO EVEROLIMUS ELUTING CORONARY STENT SYSTEM 13	ABBOTT VASCULAR	Approval for extending the shelf-life of a solvent from 4 months to 12 months.
P070027/S044	04/22/2016	Y - 135 Review Tra	TALENT OCCLUDER WITH OCCLUDER DELIVERY SYSTEM	MEDTRONIC INC.	Approval for 1) a site change for inspection and packaging/shipping of delivery system components; 2) addition of a visual inspection process; and 3) change in a detergent for machining operations.
P080025/S105	04/21/2016	N - Normal 180 Day	MEDTRONIC INTERSTIM SACRAL NERVE STIMULATION THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Approval for changes made to the Model 8840 N'Vision® Clinician Programmer including replacement of PCBA components, liquid crystal display assembly changes, compact flash card housing and programmer housing design changes, infrared data association transceiver changes, static random access memory changes, electromagnetic interference shield changes, telemetry module platform software updates, clinical programmer base module platform software updates, Physician Manual labeling changes, EMC Declaration changes, device labeling changes and packaging labeling changes.
P090013/S205	04/28/2016	N - Normal 180 Day	CAPSUREFIX MRI SURESCAN LEAD MODEL 5086MRI	MEDTRONIC INC.	Approval for the expansion of MRI conditional labeling for the Advisa and Evera SureScan systems to 3T MRI.
P090013/S205	04/28/2016	N - Normal 180 Day	CAPSUREFIX MRI SURESCAN LEAD MODEL 5086MRI	MEDTRONIC, INC	Approval for the expansion of MRI conditional labeling for the Advisa and Evera SureScan systems to 3T MRI.
P090013/S223	04/29/2016	R - Real-Time Proc	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Approval for firmware update to the MyCareLink Patient Monitor.
P100009/S016	04/05/2016	O - Normal 180 Day	MITRACLIP CLIP DELIVERY SYSTEM	ABBOTT VASCULAR INC.	Approval of the changes to the post-approval study protocol.

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P100027/S024	04/13/2016	Y - 135 Review Tra	INFORM HER2 DUAL ISH DNA PROBE COCKTAIL	VENTANA MEDICAL SYSTEMS, INC.	Approval for the following: 1) Enlargement of a bulk formulation room at Ventana Medical Systems' Tucson, AZ facility; and 2) addition of two large volume tanks, along with supply plumbing, a clean in place (CIP) procedure, and new filler, as well as a new fill line.
P100029/S021	04/24/2016	N - Normal 180 Day	TRIFECTA VALVE WITH GLIDE TECHNOLOGY	ST. JUDE MEDICAL, INC.	Approval for the addition of the Trifecta Valve with Glide Technology (Trifecta GT).
P100040/S025	04/22/2016	Y - 135 Review Tra	VALIANT THORACIC STENT GRAFT WITH CAPTIVA DELIVERY SYSTEM	MEDTRONIC INC.	Approval for 1) a site change for inspection and packaging/shipping of delivery system components; 2) addition of a visual inspection process; and 3) change in a detergent for machining operations.
P100045/S006	04/29/2016	O - Normal 180 Day	CARDIOMEMS	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P110010/S118	04/19/2016	R - Real-Time Proc	PROMUS PREMIER EVEROLIMUS-ELUTING PLANTINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for a change in colorant used in the distal tip component of the delivery catheter.
P110016/S021	04/29/2016	O - Normal 180 Day	THERAPY COOL PATH DUO ABLATION, THERAPY COOL PATH SP ABLATION CATHETER,SAFIRE BLU DUO ABLATION CATHETER,SAFIRE BLU DUO S	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.

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P110019/S080	04/27/2016	Y - 135 Review Tra	XIENCE PRIME,XIENCE XPEDITION, XIENCE ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEMS	ABBOTT VASCULAR	Approval for extending the shelf-life of a solvent from 4 months to 12 months.
P110038/S011	04/26/2016	R - Real-Time Proc	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for a shelf life extension from 3 to 4 years.
P120011/S002	04/25/2016	O - Normal 180 Day	IDEAL IMPLANT SALINE FILLED BREAST IMPLANT	IDEALIMPLANT	Approval for a change to the currently approved brand name of IDEAL IMPLANT® Saline-filled Breast Implant to IDEAL IMPLANT® Structured Breast Implant.
P120014/S006	04/05/2016	N - Normal 180 Day	THXID-BRAF KIT	BIOMERIEUX, INC.	Approval for a change in the THxID-BRAF software to detect a specific fallback threshold value within the SDS file and in such case prevent the generation of a mutation report.
P130009/S054	04/06/2016	S - Special CBE	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval for adding a new visual inspection for the Introducer component of the Edwards Ascendra+ Introducer Sheath Set.
P130022/S004	04/15/2016	N - Normal 180 Day	SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Approval for the Surgical Lead Models LEAD3005-xx, LEAD3015-xx, and LEAD3025-xx.
P130029/S002	04/26/2016	P - Panel Track	FLUENCY PLUS ENDOVASCULAR STENT GRAFT	BARD PERIPHERAL VASCULAR, INC.	Approval for the Fluency Plus Endovascular Stent Graft. This device is indicated for use in the treatment of in-stent restenosis in the venous outflow of hemodialysis patients dialyzing by either an arteriovenous (AV) fistula or AV graft and for the treatment of stenosis in the venous outflow of hemodialysis patients dialyzing by an AV graft.
P130030/S019	04/19/2016	R - Real-Time Proc	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC	Approval for a change in colorant used in the distal tip component of the delivery catheter.
P140003/S004	04/07/2016	P - Panel Track	IMPELLA VENTRICULAR SUPPORT SYSTEMS	ABIOMED, INC.	Approval for the Impella 2.5, Impella CP, Impella 5.0, and Impella LD catheters, in conjunction with the Automated Impella Controller, are temporary ventricular support devices intended for short term use (<= 4 days for the Impella 2.5 and Impella CP, and <=6 days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella System therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. *Optimal medical management and conventional measures include volume loading, use of pressors and inotropes support with or without IABP.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140003/S005	04/07/2016	P - Panel Track	IMPELLA LEFT VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC.	Approval for the Impella 2.5, Impella CP, Impella 5.0, and Impella LD catheters, in conjunction with the Automated Impella Controller, are temporary ventricular support devices intended for short term use (<= 4 days for the Impella 2.5 and Impella CP, and <=6 days for Impella 5.0 and LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (<48 hours) following acute myocardial infarction or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures.* The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function. *optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP.
P140009/S004	04/29/2016	O - Normal 180 Day	BRIO FAMILY DEEP BRAIN STIMULATION (DBS) SYSTEMS	ST. JUDE MEDICAL	Approval for a manufacturing site located at St. Jude Medical, 2305 Walnut Street, Roseville, Minnesota, 55113, for rework/relabeling of 12 class III devices.
P140020/S001	04/29/2016	R - Real-Time Proc	BRACANALYSIS CDX	MYRIAD GENETIC LABORATORIES	Approval to add additional critical instruments of the same type using approved protocols.
P140021/S002	04/12/2016	N - Normal 180 Day	ELECSYS ANTI-HCV II IMMUNOASSAY	ROCHE DIAGNOSTICS OPERATIONS INC	Approval for the migration of claims from the FDA approved Elecsys Anti-HCV II Immunoassay and Elecsys PreciControl Anti-HCV on the cobas e 601 immunoassay analyzer to the cobas e 602 analyzer. The device, as modified, will be marketed under the trade name Elecsys Anti-HCV II Immunoassay and Elecsys PreciControl Anti-HCV and is indicated for: Elecsys Anti-HCV II Immunoassay: Immunoassay for the in vitro qualitative detection of antibodies to hepatitis C virus (HCV) in human adult and pediatric (ages 18 months through 21 years) serum and plasma (potassium EDTA, lithium heparin, sodium heparin, and sodium citrate). Assay results, in conjunction with other laboratory results and clinical information, may be used to aid in the presumptive diagnosis of HCV infection in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis C infection. The test does not determine the state of infection or associated disease. The electrochemiluminescence immunoassay ECLIA is intended for use on the cobas e 601 and cobas e 602 immunoassay analyzers. Elecsys PreciControl Anti-HCV: Elecsys PreciControl Anti-HCV is used for quality control of the Elecsys Anti-HCVimmunoassay on the cobas e 601 and cobas e 602 immunoassay analyzers and the Elecsys Anti-HCV II immunoassay on the cobas e 601 and cobas e 602 immunoassay analyzers.
P140023/S003	04/25/2016	R - Real-Time Proc	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Approval for the proposed formulation change (removal of anti-microbial agent ProClin 300) and process changes to production of KRAS reaction Mix, a component of cobas® KRAS Mutation Test.
P140025/S002	04/13/2016	Y - 135 Review Tra	VENTANA ALK (D5F3) CDX ASSAY	VENTANA MEDICAL SYSTEMS, INC.	Approval for the following: 1) Enlargement of a bulk formulation room at Ventana Medical Systems' Tucson, AZ facility; and 2) addition of two large volume tanks, along with supply plumbing, a clean in place (CIP) procedure, and new filler, as well as a new fill line.

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P150003/S002	04/07/2016	O - Normal 180 Day	SYNERGY EVEROLIMUS ELUTING PLATINUM CHROMIUN CORONARY STENT SYSTEM MONORAIL & OVER THE WIRE.	BOSTON SCIENTIFIC CORP.	Approval for a manufacturing site located at Boston Scientific Maple Grove, One/Two Scimed Place, Maple Grove, Minnesota for stent finishing (electropolishing, passive inspection , and final clean).

Total: 108

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P810002/S097	04/27/2016	X - 30-Day Notice	BILEAFLET-CENTER OPENING CARDIAC VALVE	ST. JUDE MEDICAL, INC.	Shelf life extension of the conduit component of the SJM Masters Valved Graft.
P830055/S169	04/14/2016	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Introduction of an alternate manufacturing facility and the addition of a new Coordinate Measurement Machine.
P830061/S128	04/12/2016	X - 30-Day Notice	CapSure Sense Lead 4074, 4574; CapSure SP Novus Lead 4092, 4592	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a new laser welding machine.
P850089/S117	04/12/2016	X - 30-Day Notice	CapSure SP Novus Lead 5092, 5592, 5594; CapSure Z Novus Lead 5054, 5554	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Addition of a new laser welding machine.
P860003/S085	04/22/2016	X - 30-Day Notice	UVAR PHOTOPHERESIS SYSTEM	THERAKOS, INC.	Manufacturing site change for the centrifuge bowl components of the Therakos UVAR XTS Procedural Kit used in the Therakos UVAR XTS Photopheresis System.

P880086/S271	04/22/2016	X - 30-Day Notice	Verity 5056, 5156, 5256, 5356, 5456, 5816; Zephyr 5826, 5626; Identity 5286, 5386; Sustain XL PM1134, PM1136, PM2134, PM2136	ST. JUDE MEDICAL, INC.	Add an alternate supplier for the IS-1 connector assembly.
P910001/S084	04/07/2016	X - 30-Day Notice	SPECTRANECTICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORP.	Changes to the distal jacket manufacturing process.
P910018/S019	04/19/2016	X - 30-Day Notice	LIPOSORBER(R) LA-15 SYSTEM ADSORPTION COLUMN, SULFUX(R) FS-05 PLASMA SEPARATOR, AND TUB. SYST. FOR PLASMAPHER. (LT-MA2).	KANEKA PHARMA AMERICA CORP.	Implementation of a new manufacturing site for the vendor [Neat Co., Ltd.] of the GD cap component of the SULFLUX® KP-05 as part of the LIPOSORBER® LA-15 System.
P910073/S134	04/27/2016	X - 30-Day Notice	ENDOTAK RELIANCE G/SG with 4-SITE Connector Defibrillation Leads, Passive Fixation Lead Models: 0265, 0266, 0282, 0283, 0285, 0286; Active Fixation Lead Models: 0275, 0276, 0292, 0293, 0295, 0296	BOSTON SCIENTIFIC	Implementation of a new laser weld system.
P920015/S176	04/04/2016	X - 30-Day Notice	Sprint Quattro Lead 6946M; Sprint Quattro Lead 6935, 6935M, 6944, 6947, 6947M	MEDTRONIC INC.	Removal of the use of clean benches in the high voltage sterile pack manufacturing area.
P930014/S089	04/01/2016	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Use of a new Multi-piece Auto-dimensional Measurement System to conduct final dimensional inspection of the AcrySof multi-piece intraocular lenses.
P930014/S090	04/28/2016	X - 30-Day Notice	ACRYSOF (R) UV ABSORBING INTRAOCULAR LENSES	ALCON RESEARCH, LTD.	Use of an automated process for injecting the AcrySof® material into intraocular lens wafers in place of the current manual casting system.
P930038/S080	04/25/2016	X - 30-Day Notice	ANGIO-SEAL VASCULAR CLOSURE DEVICE	ST. JUDE MEDICAL, INC.	Automate the puncture locator and sheath annealing cycle verification process.
P930039/S150	04/18/2016	X - 30-Day Notice	CapSureFix Novus Lead 5076; Vitatron Crystalline	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for the electrode ring and helix assembly.
P940015/S036	04/04/2016	X - 30-Day Notice	SYNVISC ONE	GENZYME CORP.	Process change to add a qualified raw material supplier for frozen sliced chicken combs used in the manufacturing process of hylan G-F20.

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P950005/S060	04/25/2016	X - 30-Day Notice	EZ Steer DS Bi-Directional Catheter,EZ Steer Bi-Directional CatheterABLATION, Celsius Flutter Bi-Directional Catheter	CORDIS CORP.	Implementation of a new pouch sealer to be used in the approved facility to seal the primary pouch for the catheter product codes.
P960013/S080	04/28/2016	X - 30-Day Notice	Tendril ST 1888/1882 TC; Tendril STS 2088 TC; Optisense 1999	PACESETTER, INC.	Alternate supplier for the lead connector boot.
P960016/S063	04/12/2016	X - 30-Day Notice	LIVEWIRE(R) CARDIAC ABLATION SYSTEM	St. Jude Medical	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P960030/S043	04/28/2016	X - 30-Day Notice	IsoFlex 1944, 1948	PACESETTER, INC.	Alternate supplier for the lead connector boot.
P960040/S367	04/20/2016	X - 30-Day Notice	VENTAK AV AICD VENTAK PRIZM DR/VR, VITALITY, COFIENT, AND TELIGEN AUTOMATIC IMPLANTABLE CARDIOVETER DEFIBRILLATOR SYSTEM	BOSTON SCIENTIFIC	Changes to a fixture used in the manufacturing of electronic assembly hybrids.
P960040/S368	04/14/2016	X - 30-Day Notice	Dynagen, Inogen, Origen Implantable Cardiac Defibrillators (ICDs)	BOSTON SCIENTIFIC	Update work instructions for the manufacturing inspection process to define acceptable criteria for a cosmetic defect in high voltage capacitors.
P980016/S580	04/13/2016	X - 30-Day Notice	VIRTUSO/ENTRUST/ MAXIMO/INTRINSIC/ MARQUIS/IMPLANTABLE CARDIVERTER DEFIBRILLATORS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of changes to the hybrid assembly and inspection process.
P980016/S583	04/05/2016	X - 30-Day Notice	CONTINUOUS GLUCOSE MONITORING SYSTEM	MEDTRONIC MINIMED	Relocation of a contract manufacturing facility for printed circuit boards and board stack assemblies used in all Medtronic MiniMed Paradigm Real-Time Revel insulin pumps, Paradigm Real-Time insulin pumps, and MiniMed 530G insulin pumps. The firm is also requesting changes in the manufacturing process sequence as well as updates to mechanical drawings to add vendor name and pump models. The Paradigm Real-Time insulin pumps are a component of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and the Paradigm Real-Time Revel System with Enlite Sensor. The MiniMed 530G insulin pumps are a component of the MiniMed 530G System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980022/S191	04/21/2016	X - 30-Day Notice	CONTINUOUS GLUCOSE MONITORING SYSTEM	MEDTRONIC MINIMED	Transfer of equipment used for environmental conditioning for printed circuit board assemblies from Medtronic MiniMed in Northridge, CA to Medtronic Puerto Rico Operations Co. (MPROC), Juncos, PR. The circuit board assemblies are used in the Paradigm family of insulin pumps which are components of the Paradigm REAL-Time System, Paradigm REAL-Time Revel System, Paradigm REAL-Time Revel System with Enlite Sensor, and the MiniMed 530G System.
P980035/S459	04/08/2016	X - 30-Day Notice	MEDTRONIC KAPPA 700/600 SERIES PULSE GENERATORS AND MODEL 9953 SOFTWARE	MEDTRONIC INC.	Update to the resistance spot weld equipment used to manufacture battery assemblies.
P980035/S461	04/22/2016	X - 30-Day Notice	Adapta, Versa, Sensia IPG ADDR01, ADDRL1, ADDRS1, SEDR01, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01, ADSR01, ADVDD01; Advisa DR IPG A4DR01; Advisa DR MRI IPG A2DR01; Advisa SR MRI IPG A3SR01; Relia IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	Add an alternate material for a manufacturing gauge tool.
P990004/S029	04/07/2016	X - 30-Day Notice	SURGIFOAM ABSORBABLE GELATIN SPONGE,U.S.P.	ETHICON, INC.	Installation of two separate photocells on the multivac equipment that packs SURGIFOAM® Oral Sponge products.
P990025/S048	04/25/2016	X - 30-Day Notice	NAVI-STAR and EZ Steer Nav Bi-Directional Catheter	BIOSENSE WEBSTER, INC.	Implementation of a new pouch sealer to be used in the approved facility to seal the primary pouch for the catheter product codes.
P990075/S036	04/15/2016	X - 30-Day Notice	MENTOR CORPORATION SALINE-FILLED AND SPECTRUM (R) MAMMARY PROSTHESES	MENTOR WORLDWIDE LLC	Update to the PROC000331 Packaging with Alloyd Heat Sealers and Tyvek Pouch to implement the use of Nilfisk GM80 CR Vacuum Cleaner around the heat sealers as a manufacturing aid to remove potential debris from equipment crevices.
P000039/S054	04/12/2016	X - 30-Day Notice	THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM	AGA MEDICAL CORP.	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P010003/S020	04/07/2016	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Modified cartoning and labeling process.
P010003/S021	04/27/2016	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	implementation of an autotitrator for the determination of glutaraldehyde concentration and an alternate gel for SDS-PAGE testing.

P010012/S413	04/20/2016	X - 30-Day Notice	CONTAK CD,EASYTRAK, LIVIAN, COGNIS AND ACUITY SPIRIAL AUTOMATIC IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLL	BOSTON SCIENTIFIC CORP.	Changes to a fixture used in the manufacturing of electronic assembly hybrids.
P010012/S414	04/14/2016	X - 30-Day Notice	Dynagen, Inogen, Origen Cardiac Resynchronization Therapy Defibrillators (CRT-Ds)	BOSTON SCIENTIFIC CORP.	Update work instructions for the manufacturing inspection process to define acceptable criteria for a cosmetic defect in high voltage capacitors.
P010014/S054	04/26/2016	X - 30-Day Notice	OXFORD(TM) MENISCAL UNICOMPARTMENTAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Addition of a new wax supplier.
P010015/S296	04/08/2016	X - 30-Day Notice	MEDTRONIC INSYNC(TM) BIVENTRICAL PACING SYSTEM	MEDTRONIC INC.	Update to the resistance spot weld equipment used to manufacture battery assemblies.
P010015/S298	04/22/2016	X - 30-Day Notice	Consulta CRT-P C4TR01; Syncra CRT-P C2TR01; Viva CRT-P C6TR01	MEDTRONIC INC.	Add an alternate material for a manufacturing gauge tool.
P010031/S541	04/13/2016	X - 30-Day Notice	CONCERTO/INSYNC SENTRY/INSYNC MAXIMO IMPLANTABLE CARDIOVASCULAR DEFIBRILLATORS WITH CARDIAC RESYNCHICNIZATION	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of changes to the hybrid assembly and inspection process.

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P010031/S544	04/22/2016	X - 30-Day Notice	Amplia MRI CRT-D DTMB1D4; Amplia MRI Quad CRT-D DTMB1QQ; Brava CRT-D DTBC1D4, DTBC1D1; Brava Quad CRT-D DTBC1Q1, DTBC1QQ; Compia MRI CRT-D DTMC1D4; Compia MRI Quad CRT-D DTMC1QQ; Concerto II CRT-D D274TRK; Consulta CRT-D D204TRM, D224TRK; Maximo II CRT-D D264TRM, D284TRK; Protecta CRT-D D334TRM, D334TRG; Protecta XT CRT-D D314TRM, D314TRG; Viva Quad S CRT-D DTBB1Q1, DTBB1QQ; Viva Quad XT CRT-D DTBA1Q1, DTBA1QQ; Viva S CRT-D DTBB1D1, DTBB1D4; Viva XT CRT-D DTBA1D1, DTBA1D4	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Add an alternate material for a manufacturing gauge tool.
P010032/S114	04/20/2016	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	St. Jude Medical	Change to the electrode manufacturing process and a replacement of 100% inspection with an AQL sampling plan for the Spinal Cord Stimulation (SCS) and Deep Brain Stimulation (DBS) leads, extensions, and adapters.
P010032/S116	04/29/2016	X - 30-Day Notice	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	St. Jude Medical	Introduction of automated test equipment to measure the pull force for the removal of a stylet from a lead.

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P010033/S028	04/27/2016	X - 30-Day Notice	QUANTTFERON-TB GOLD AND TB GOLD-IN-THE-TUBE	QIAGEN	Addition of a component manufacturing site.
P010068/S050	04/25/2016	X - 30-Day Notice	NAVISTAR DS CATHETER, EZ Steer Nav DS Bi-Directional Catheter	BIOSENSE WEBSTER, INC.	Implementation of a new pouch sealer to be used in the approved facility to seal the primary pouch for the catheter product codes.
P020004/S127	04/07/2016	X - 30-Day Notice	EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of new extruder equipment for manufacturing the base tube component of the GORE® EXCLUDER® AAA Endoprosthesis.
P020004/S128	04/08/2016	X - 30-Day Notice	EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of two additional catheter part numbers on an existing GORE EXCLUDER AAA Endoprosthesis SIM-PULL catheter manufacturing line in Gores Phoenix facility.
P020004/S129	04/04/2016	X - 30-Day Notice	EXCLUDER BIFURCATED ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Alternative manufacturing process for the tubular sleeves in the manufacture of the GORE EXCLUDER Iliac Branch Endoprosthesis.
P020024/S043	04/12/2016	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	AGA MEDICAL CORP.	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P020024/S044	04/12/2016	X - 30-Day Notice	AMPLATZER DUCT OCCLUDER AND 180 DEGREE DELIVERY SYSTEM	AGA MEDICAL CORP.	Change in the oven used to form the AMPLATZER Duct Occluder.
P020025/S085	04/08/2016	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Addition of an alternate vendor for components that are utilized in electrophysiology catheters.
P020025/S086	04/19/2016	X - 30-Day Notice	EP TECHNOLOGIES EPT-1000 XP RF ABLATION SYSTEM	BOSTON SCIENTIFIC	Acceptance of an alternate vendor for the IntellaNav XP and IntellaNav MiFi XP temperature ablation catheter tips.
P020036/S036	04/20/2016	X - 30-Day Notice	S.M.A.R.T. AND S.M.A.R.T. CONTROL NITINOL STENT SYSTEM	CORDIS CORP.	Supplier site change.
P030009/S085	04/13/2016	X - 30-Day Notice	DRIVER OVER-THE-WIRE, RAPID EXCHANGE, AND MULTI-EXCHANGE CORONARY STENT SYSTEMS	MEDTRONIC IRELAND	Change to the sterilization monitoring process.

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P030017/S249	04/01/2016	X - 30-Day Notice	PRECISION SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Acceptance of an alternate qualified supplier for the Ball Grid Assemblies (BGA) that are used in the Precision Novi Implantable Pulse Generators.
P030031/S073	04/25/2016	X - 30-Day Notice	BIOSENSE WEBSTER NAVISTAR/CELSIUS THERMO COOL DIAGNOSTIC/ABLATION DEFLECTABLE TIP CATHETERS	BIOSENSE WEBSTER, INC.	Implementation of a new pouch sealer to be used in the approved facility to seal the primary pouch for the catheter product codes.
P030047/S032	04/20/2016	X - 30-Day Notice	CORDIS PRECISE NITINOL STENT SYSTEM	CORDIS CORP.	Supplier site change.
P030053/S033	04/15/2016	X - 30-Day Notice	MEMORYGEL SILICONE GEL -FILLED BREAST IMPLANTS	MENTOR CORP.	Update to the PROC000331 Packaging with Alloyd Heat Sealers and Tyvek Pouch to implement the use of Nilfisk GM80 CR Vacuum Cleaner around the heat sealers as a manufacturing aid to remove potential debris from equipment crevices.
P040005/S013	04/12/2016	X - 30-Day Notice	DAKOCYTOMATION HER2 FISH PHARMDX KIT	DAKO DENMARK A/S	Changes to the DNA propagation and purification processes.
P040020/S061	04/01/2016	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Use of a new Multi-piece Auto-dimensional Measurement System to conduct final dimensional inspection of the AcrySof Restor Multi-Piece intraocular lenses.
P040020/S063	04/28/2016	X - 30-Day Notice	ACRYSOF RESTOR APODIZED DIFFRACTIVE OPTIC POSTERIOR CHAMBER IOL	ALCON RESEARCH, LTD.	Use of an automated process for injecting the AcrySof® material into intraocular lens wafers in place of the current manual casting system.
P040036/S054	04/25/2016	X - 30-Day Notice	THERMOCOOL SMART TOUCH UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Implementation of a new pouch sealer to be used in the approved facility to seal the primary pouch for the catheter product codes.
P040037/S090	04/07/2016	X - 30-Day Notice	VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Replacement of a raw material resin.
P040040/S027	04/12/2016	X - 30-Day Notice	AMPLATZER MUSCULAR VSD OCCLUDER	AGA MEDICAL CORP.	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P040043/S083	04/06/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Supplier process change for the Conformable GORE TAG Thoracic Endoprosthesis delivery system hub.
P040043/S084	04/22/2016	X - 30-Day Notice	GORE TAG THORACIC ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of an automated laser for use in cutting the graft of the GORE TAG Thoracic Endoprosthesis.

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P050018/S021	04/26/2016	X - 30-Day Notice	ANGIOSCULPT SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Change to the Limulus amebocyte lysate (LAL) bacterial endotoxin test program.
P050028/S050	04/29/2016	X - 30-Day Notice	COBAS TAQMAN HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P060030/S050	04/29/2016	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P060037/S044	04/29/2016	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	to discontinue redundant in-house testing of Ultra High Molecular Weight Polyethylene (UHMWPE) used in the LPS-Mobile Articular Surface components (i.e., tibial inserts) upon its receipt at Zimmer
P060038/S027	04/27/2016	X - 30-Day Notice	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Addition of a new bovine pericardial tissue supplier.
P060040/S055	04/28/2016	X - 30-Day Notice	THORATEC HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM	THORATEC CORP.	Add a new sterilization chamber for certain components of the Thoratec HeartMate II® Ventricular Assist System.
P080006/S091	04/14/2016	X - 30-Day Notice	MEDTRONIC ATTAIN ABILITY MODEL 4196 LEAD	MEDTRONIC INC.	Implementation of changes to the molded ring monolithic controlled release device (MCRD) wash process.
P080011/S042	04/05/2016	X - 30-Day Notice	BIOFINITY (COMFILCON A)	COOPERVISION MANUFACTURING, LTD.	Biofinity Line 17 to manufacture Biofinity Energys Asphere (comfilcon A) minus power lenses within the approved range.
P080026/S017	04/12/2016	X - 30-Day Notice	ABBOTT REALTIME HBV ASSAY	ABBOTT MOLECULAR, INC.	Change to consolidate the current QC testing for the Amplification Reagent Kit from two stages into a single finished kit QC stage.
P090013/S222	04/08/2016	X - 30-Day Notice	REVO MRI SURESCAN IPG AND PACING SYSTEM	MEDTRONIC, INC	Update to the resistance spot weld equipment used to manufacture battery assemblies.
P090013/S224	04/22/2016	X - 30-Day Notice	Revo MRI SureScan IPG RVDR01	MEDTRONIC, INC	Add an alternate material for a manufacturing gauge tool.
P090016/S020	04/11/2016	X - 30-Day Notice	BELOTERO BALANCE	MERZ NORTH AMERICA, INC	Change to the conduct of the BDDE test assay.

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P100017/S015	04/20/2016	X - 30-Day Notice	ABBOTT REALTIME HCV, ABBOTT REALTIME HCV AMPLIFICATION REAGENT KIT, ABBOTT REALTIME HVC CONTROL KIT, ABBOTT REALTIME HCV	ABBOTT MOLECULAR, INC.	Addition of a new purified water source and a new supplier of a raw material used in the production of bulk reagents.
P100017/S016	04/12/2016	X - 30-Day Notice	ABBOTT REALTIME HCV, ABBOTT REALTIME HCV AMPLIFICATION REAGENT KIT, ABBOTT REALTIME HVC CONTROL KIT, ABBOTT REALTIME HCV	ABBOTT MOLECULAR, INC.	Change to consolidate the current QC testing for the Amplification Reagent Kit from two stages into a single finished kit QC stage.
P100020/S018	04/29/2016	X - 30-Day Notice	COBAS HPV TEST	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P100022/S017	04/14/2016	X - 30-Day Notice	ZILVER PTX DRUG-ELUTING PERIPHERAL STENT	COOK MEDICAL INCORPORATED	Changes made by a supplier of a critical component.
P100024/S009	04/12/2016	X - 30-Day Notice	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	Changes to the DNA propagation and purification processes.
P110013/S064	04/14/2016	X - 30-Day Notice	RESOLUTE MICROTRAC/ RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Addition of a degasser to the spray machine currently in use for the drug spray process.
P110016/S030	04/12/2016	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC.	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P110016/S031	04/14/2016	X - 30-Day Notice	THERAPY COOL PATH DUO/ SAFIRE BLU DUO ABLATION CATHETER AND IBI 1500T9-CP V1.6 CARDIAC ABLATION GENERATOR	ST. JUDE MEDICAL, INC.	Supplier manufacturing changes (facility, welding equipment, and cleaning solvent) for the catheter components of the Therapy Cool Flex and FlexAbility Ablation Catheters.

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P110019/S083	04/15/2016	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Improvement to the laser welder task sequence by adding a safety light curtain circuit.
P110019/S084	04/15/2016	X - 30-Day Notice	XIENCE PRIME AND XIENCE PRIME LL EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change the sampling plan for annual stability of the repackaged drug substance.
P110023/S018	04/20/2016	X - 30-Day Notice	EVERFLEX SELF-EXPANDING PERIPHERAL STENT SYSTEM (EVERFLEX)	MEDTRONIC VASCULAR INC	Alternative stent laser cutting system.
P110029/S023	04/06/2016	X - 30-Day Notice	ARCHITECT HBSAG QUALITATIVE, QUALITATIVE CONFIRMATORY, CONFIRMATORY MANUAL DILUENT, CALIBRATORS, AND CONTROLS	ABBOTT LABORATORIES	Relocation of manufacturing activities for the purification and production of antibodies used in final test components.
P110037/S025	04/29/2016	X - 30-Day Notice	COBAS® AMPLIPREP/ COBAS® TAQMAN® CMV TEST (CAP/CTM CMV TEST)	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P120002/S012	04/20/2016	X - 30-Day Notice	SMA RT CONTROL AND SMART VASCULAR STENT SYSTEMS	CORDIS CORP.	Supplier site change.
P120005/S046	04/21/2016	X - 30-Day Notice	DEXCOM G4 PLATINUM CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Qualification of additional manufacturing space for the manufacture of the G5 Mobile Transmitter. The G5 Mobile Transmitter is a component of the G5 Mobile Continuous Glucose Monitoring System.
P120010/S084	04/05/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Relocation of a contract manufacturing facility for printed circuit boards and board stack assemblies used in all Medtronic MiniMed Paradigm Real-Time Revel insulin pumps, Paradigm Real-Time insulin pumps, and MiniMed 530G insulin pumps. The firm is also requesting changes in the manufacturing process sequence as well as updates to mechanical drawings to add vendor name and pump models. The Paradigm Real-Time insulin pumps are a component of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and the Paradigm Real-Time Revel System with Enlite Sensor. The MiniMed 530G insulin pumps are a component of the MiniMed 530G System.

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P120010/S085	04/07/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Use the adhesive patches supplied for use on the automated assembly line on the manual line and to use a tool in order to facilitate this change in the Enlite sensors assembly process at Medtronic Puerto Rico Operations Company (MPROC). The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor.
P120010/S086	04/21/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Transfer of equipment used for environmental conditioning for printed circuit board assemblies from Medtronic MiniMed in Northridge, CA to Medtronic Puerto Rico Operations Co. (MPROC), Juncos, PR. The circuit board assemblies are used in the Paradigm family of insulin pumps which are components of the Paradigm REAL-Time System, Paradigm REAL-Time Revel System, Paradigm REAL-Time Revel System with Enlite Sensor, and the MiniMed 530G System.
P120010/S087	04/21/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Additional Plasma Cleaning System to increase the cleaning capacity of the Enlite components at Medtronic Puerto Rico Operations Company (MPROC). The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor.
P120010/S088	04/27/2016	X - 30-Day Notice	MINIMED 530G SYSTEM	MEDTRONIC INC.	Change to incorporate a step that allows the operators to wipe excess Glucose Oxidase (GOx) material from the plate during Enlite glucose sensor manufacturing. The Enlite glucose sensor is a component of the MiniMed 530G System, and the Paradigm REAL-Time REVEL System with Enlite Sensor.
P120012/S011	04/20/2016	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II, ABBOTT REALTIME HCV GENOTYPE II CONTROL KIT, URACIL-N-GLYCOSYLASE (UNG)	ABBOTT MOLECULAR	Addition of a new purified water source and a new supplier of a raw material used in the production of bulk reagents.
P120012/S012	04/12/2016	X - 30-Day Notice	ABBOTT REALTIME HCV GENOTYPE II, ABBOTT REALTIME HCV GENOTYPE II CONTROL KIT, URACIL-N-GLYCOSYLASE (UNG)	ABBOTT MOLECULAR	Change to consolidate the current QC testing for the Amplification Reagent Kit from two stages into a single finished kit QC stage.
P130006/S029	04/07/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Replacement of a raw material resin.
P130009/S052	04/13/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Modify the method used to inspect the distance between the catheter marker bands.
P130011/S004	04/27/2016	X - 30-Day Notice	FREEDOM SOLO STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Addition of a new bovine pericardial tissue supplier.
P130013/S006	04/05/2016	X - 30-Day Notice	WATCHMAN LEFT ATRIAL APPENDAGE (LAA) CLOSURE TECHNOLOGY	BOSTON SCIENTIFIC CORP.	Process improvements to the implant forming process.

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P130017/S007	04/20/2016	X - 30-Day Notice	COLOGUARD	EXACT SCIENCES CORPORATION	Relocation within current facility of manual dispensing, label printing, and kitting activities.
P130022/S006	04/15/2016	X - 30-Day Notice	NEVRO SENZA SPINAL CORD STIMULATION (SCS) SYSTEM	NEVRO CORPORATION	Process changes to the manufacture of the spinal cord stimulator system battery charger, including the addition of an adhesive to a component on the printed circuit board (PCB), minor alterations to the PCB layout to improve manufacturability, and the addition of torque wrenches to its manufacturing process.
P130026/S019	04/12/2016	X - 30-Day Notice	TACTICATH QUARTZ SET	St. Jude Medical	Addition of two new ethylene oxide sterilization chambers at the approved contract sterilizer.
P140009/S013	04/20/2016	X - 30-Day Notice	BRIO NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL NEUROMODULATION	Change to the electrode manufacturing process and a replacement of 100% inspection with an AQL sampling plan for the Spinal Cord Stimulation (SCS) and Deep Brain Stimulation (DBS) leads, extensions, and adapters.
P140010/S016	04/19/2016	X - 30-Day Notice	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Modifications to the annual stability protocol.
P140028/S009	04/12/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	Boston Scientific Corporation	New electropolishing equipment, cleaning equipment, and manufacturing data management system.
P140030/S002	04/13/2016	X - 30-Day Notice	ASTRON PERIPHERAL SELF-EXPANDING NITINOL STENT SYSTEM	BIOTRONIK, INC.	Change to the cleaning process and solution during stent manufacturing.
P150003/S008	04/08/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	Boston Scientific Corporation	Changes to the sub-assembly trimming process.

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P150003/S008	04/08/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to the sub-assembly trimming process.
P150005/S003	04/05/2016	X - 30-Day Notice	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Transfer of a production site for extruded components.
P150011/S003	04/27/2016	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Addition of a new bovine pericardial tissue supplier.
P150011/S004	04/29/2016	X - 30-Day Notice	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Changes to the incoming inspection of a component used to manufacture the device stent.
P150014/S002	04/29/2016	X - 30-Day Notice	COBAS HBV TEST	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P150015/S002	04/29/2016	X - 30-Day Notice	COBAS HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	New higher capacity oven for the manufacture of a bulk component used in the COBAS® system devices.
P150019/S009	04/05/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Relocation of a contract manufacturing facility for printed circuit boards and board stack assemblies used in all Medtronic MiniMed Paradigm Real-Time Revel insulin pumps, Paradigm Real-Time insulin pumps, and MiniMed 530G insulin pumps. The firm is also requesting changes in the manufacturing process sequence as well as updates to mechanical drawings to add vendor name and pump models. The Paradigm Real-Time insulin pumps are a component of the Paradigm Real-Time System, Paradigm Real-Time Revel System, and the Paradigm Real-Time Revel System with Enlite Sensor. The MiniMed 530G insulin pumps are a component of the MiniMed 530G System.
P150019/S010	04/07/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Use the adhesive patches supplied for use on the automated assembly line on the manual line and to use a tool in order to facilitate this change in the Enlite sensors assembly process at Medtronic Puerto Rico Operations Company (MPROC). The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor.
P150019/S011	04/21/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Transfer of equipment used for environmental conditioning for printed circuit board assemblies from Medtronic MiniMed in Northridge, CA to Medtronic Puerto Rico Operations Co. (MPROC), Juncos, PR. The circuit board assemblies are used in the Paradigm family of insulin pumps which are components of the Paradigm REAL-Time System, Paradigm REAL-Time Revel System, Paradigm REAL-Time Revel System with Enlite Sensor, and the MiniMed 530G System.
P150019/S012	04/21/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Additional Plasma Cleaning System to increase the cleaning capacity of the Enlite components at Medtronic Puerto Rico Operations Company (MPROC). The Enlite sensor is a component of the MiniMed 530G System and the Paradigm Real-Time Revel System with Enlite Sensor.

P150019/S013	04/27/2016	X - 30-Day Notice	PARADIGM REAL-TIME REVEL SYSTEM	MEDTRONIC MINIMED	Change to incorporate a step that allows the operators to wipe excess Glucose Oxidase (GOx) material from the plate during Enlite glucose sensor manufacturing. The Enlite glucose sensor is a component of the MiniMed 530G System, and the Paradigm REAL-Time REVEL System with Enlite Sensor.

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